

NAPHTHALENE

- an update -

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JPH: TSERAWG (20Sep06)

OUTLINE

- Naphthalene “State of the Science Symposium”
- Mitretek Paper
- Outline of Industry’s Approach
- AFIOH’s Tox & Epi Workshop

NAPHTHALENE

“State of the Science Symposium”

- Scheduled for 9-12Oct06, Monterey, CA
- Recruited distinguished roster of independent researchers
 - & naphthalene experts for a circumspect accounting of what is known/unknown
- Focused around 4 basic issues/themes
 - Animal data
 - Human data
 - Anatomy, physiology, metabolic activation/deactivation
 - Mechanisms of carcinogenesis
 - +Uncertainty analysis
- Guidance on best directions for research

MITRETEK PAPER

Carcinogenicity of Naphthalene - Commentary & Suggestions

- OSD tasker to clarify/highlight issues, data gaps, possible studies to address areas of uncertainty
 - Intended for submission to NS³ & EPA
- Issues, data gaps & uncertainties
 - Are the NTP studies unconfounded?
 - Is the rodent model pertinent & predictive of human risk?
 - Is the LMS model the appropriate tool, or is N a threshold carcinogen? Or both...?
 - What does epidemiology, and our experience, tell us?
- Suggestions for research/studies to clarify areas of uncertainty
- Finalize & clear with OSD & legal, etc.; submit to NS³

INDUSTRY'S PERSPECTIVE

- *ad hoc* Naphthalene Coalition -

- Supportive of NS₃
 - Watching the symposium's development closely
 - Will assess the symposium's results carefully
- Drafting outline for a research plan
 - Addresses: short term & long term research needs
data insufficiencies
regulatory uncertainty factors
 - Elements: exposure assessment, classic epidemiology, molecular epidemiology, genotoxicity, mechanism & mode of action, toxicology
 - Lessons learned from chloracetanilide pesticide MOA program
- Under development/review for submission to NS₃

AFIOH-SPONSORED 1-DAY WORKSHOP

“Naphthalene: exposure, epidemiology, human effects & cancer”

- Point of focus – seeming lack of epidemiological evidence for naphthalene-related cancer in humans
 - Different parties each had pieces of an incomplete puzzle
 - Assembled sampling of gov & industry experts
 - Morning: share & compare what we know
highlight what we don't know
 - Afternoon: generate issues/suggestions for research on uncertainties pertinent to improving naphthalene's risk assessment
 - Action items identified
 - Meeting summary forthcoming
- Support for submission to NS³

QUESTIONS?